LAW OFFICES

HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W.

SUITE 1200

WASHINGTON, D. C. 20005-5929

(202) 737-5600

FACSIMILE (202) 737-9329

www.hpm.com

JENNIPER B. DAVIS OF COUNSEL

DAVID B. CLISSOLD
CASSANDRA A. SOLTIS
JOSEPHINE M. TORRENTE
MICHELLE L. BUTLER
ANNE MARIE MURPHY
PAUL L. FERRARI
JEFFREY N. WASSERSTEIN
MICHAEL D. BERNSTEIN
LARRY K. HOUCK
DARA S. KATCHER®
KURT R. KARST
MOLLY C. ANDRESEN
SHAWN M. BROWN®

THOU ADMITTED IN DC

DIRECT DIAL (202) 737-4291

June 22, 2004

By Facsimile/Confirmation by Mail

Mr. Christian Gimber Wacker Chemical Corporation 3301 Sutton Road Adrian, Michigan 49221-9397

Dear Mr. Gimber:

JAMES R. PHELPS

ROBERT A. DORMER STEPHEN H. MCNAMARA

ROGER C. THIES THOMAS SCARLETT

JEFFREY N. GIBBS

FRANK J. SASINOWSKI

ALAN M. KIRSCHENBAUM

DOUGLAS B. FARQUHAR

JOHN A. GILBERT, JR.

(1945-1996)

A. WES SIEGNER, JR.

BRIAN J. DONATO

DIANE B. MCCOLL

JOHN R. FLEDER

FRANCES K. WU ROBERT T. ANGAROLA

MARC H. SHAPIRO

PAUL M. HYMAN

You have asked whether the a-cyclodextrin manufactured by Wacker Chemical Corporation (Wacker) may be legally marketed in the United States for food use. The answer is yes, Wacker's a-cyclodextrin may be marketed immediately for use in foods.

As you know, many substances added to foods are not food additives and do not require approval by the Food and Drug Administration (FDA) prior to use. These substances, popularly known as "GRAS" substances, are considered to be "generally recognized as safe." As stated in the Federal Food, Drug, and Cosmetic Act (FDC Act), a GRAS substance is

generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

2603 MAIN STREET SUITE 760 IRVINE, CALIFORNIA 92614 19491 553-7400 FAX: 19491 553-7433 4819 EMPEROR BOULEVARD SUITE 400 DURHAM, NORTH CAROLINA 27703 (910) 313-4750 FAX: (910) 313-4751 21 U.S.C. § 321(s). If a substance is found to be GRAS under the intended conditions of use, FDA approval or notification is not required prior to such use. FDA acknowledges that "under the 1958 amendment [to the FDC Act], a substance that is GRAS for a particular use may be marketed for that use without agency review and approval." 62 Fed. Reg. 18938, 18939 (April 17, 1997). FDA also recognizes that companies "have the right to make independent GRAS determinations on food substances." 53 Fed. Reg. 16544, 16545 (May 10, 1988).

A specially-convened independent panel of qualified scientific experts recently evaluated Wacker's α-cyclodextrin for use in foods. After a critical review of the scientific evidence, including, e.g., physical and chemical identity information, Wacker's manufacturing process, publicly available safety data, corroborating unpublished safety data, the intended uses and consumption estimates, the Expert Panel concluded that, based on scientific procedures, Wacker's α-cyclodextrin is GRAS under the conditions of its intended use in foods.

Accordingly, based on its GRAS status, Wacker's α-cyclodextrin may be legally marketed for the conditions of use in foods that were evaluated by the Expert Panel,

We trust that these comments are responsive to your inquiry. If you have any further questions, please do not hesitate to contact us.

Sincerely,

Diane B. McColl

Diane B. We Coll

DBM/hfm